

Remarks

Reconsideration and allowance of the subject patent application are respectfully requested.

Applicants' representative wishes to thank Examiner Kianni for the courtesy extended during the interview on November 12, 2003 discussing the subject application. The substance of the interview is contained in the following remarks.

Claims 22-41 are alleged to be directed to inventions that are independent or distinct from the invention originally claimed. Claims 22-41 are canceled without prejudice or disclaimer. Because a restriction requirement is never proper unless the restricted groups of claims are patentably distinct (*i.e., inter alia*, non-obvious under 35 U.S.C. Section 103) from the elected group of claims, the Examiner is requested to ensure that such patentable distinctness is present before proceeding to make the requirement final. Applicants reserve the right to file divisional application(s) directed to the subject matter of the non-elected inventions.

Certain claims have been amended to improve their form. These amendments are not made for reasons relating to patentability.

Claims 1-7 and 12-20 were rejected under 35 U.S.C. Section 103(a) as allegedly being obvious over Wu *et al.* (U.S. Patent No. 5,452,723). Because the claimed systems and methods are in no way shown or suggested by Wu *et al.*, Applicants traverse this rejection.

First, the subject patent application discloses a system and method for determining optical characteristics such as the absorption coefficient μ_a , the reduced scattering coefficient μ_s , and a parameter γ from the spatially resolved reflectance $R(\rho)$. This determination involves, among other things, the dependence of the diffuse reflectance R on the distance ρ separating the source of illumination and the optical detector. This dependence of R on ρ does not at all appear in Wu *et al.* The diffuse reflectance $R(\mu_a, \mu_s, g)$ of Wu *et al.* is a value of the reflectance integrated over space and does not contain any information on its dependence on the source-detector distance ρ . In addition, although the office action refers to the "z" described in column 8 of Wu *et al.* as

the "source-detector distance," "z" actually refers to tissue depth. *See, e.g.*, col. 8, line 9-11.

More specifically, according to the Figure 4 description in Wu *et al.*, the role of the fiber or fiber bundle 46 is to collect the induced emission from tissue sample 29. The description suggests that any and possibly all the emissions from tissue sample are collected by fiber or fiber bundle 46, without discrimination of the emitting part of the sample. More precisely, Wu *et al.* makes no arrangement to isolate the emission from some particular part of the sample, thereby precluding Wu *et al.* from the possibility of achieving spatially resolved reflectance measurements. For example, the arrangement of the receiving fiber 46 with respect to the emitting fiber 40 is not specified from the point of view of the distance therebetween. The only requirement mentioned is that specular reflection from the interface 45 between the catheter 28 and tissue 29 should be avoided by a convenient angulation of the delivery fiber 40 and collecting fiber 46. This consideration clearly demonstrates that spatially resolved measurements of reflectance are of no concern in Wu *et al.*

The dependence of the average diffuse intensity U_d on the depth z in the tissue (col. 8, line 10) is introduced for the development of the model provided by the so-called "Diffusion Theory". The only result concerns the calculation of the diffuse flux at the tissue surface ($z=0$) (equation (6)). The z dependence of the diffuse intensity is of no relevance in the experimental measurements, nor does z in any way refer to the source-detector distance as erroneously alleged on page 4 of the office action. Moreover it is specified that the prediction concerning the diffuse reflectance R at $z=0$ do not involve any spatial dependence and is only used to compare the results of this analytical approach to photon migration theory and Monte Carlo calculation (col.8, lines 53-55).

In summary, contrary to the assertions in the office action, there is no disclosure or suggestion in Wu *et al.* of spatially-resolved reflectance, much less of using the reflectance in the manner set forth in the claims.

Second, the parameter $\gamma = (1 - g_2)/(1 - g_1)$ described in the subject patent application and specified in claim 1 is a new concept and is not related to g and g' appearing in equation 13 of Wu *et al.*: $k(g')/k(g) = 1 - g'/1 - g$. Specifically, g and g' are both first order moments, whereas g_1 and g_2 are respectively the first and second order

moments of the development of the phase function $p(\theta)$ in Legendre polynomials. Consequently, the parameter γ and equation 13 of Wu *et al.* are quite different. Indeed, Wu *et al.* does not mention the second order moment of the phase function. The approach of the subject application is fundamentally different and cannot be derived from Wu *et al.*'s approach. The parameter γ does merely involve a change in terminology as alleged on page 12 of the office action, but is rather a new concept that is not at all apparent from Wu *et al.*

More specifically, the first two terms of the Legendre expansion are the moment of zeroth order, g_0 (normalization factor), and the moment of first order, g_1 (anisotropy factor). Wu *et al.* conforms to the well-known "diffusion approximation", which corresponds to a development of the first order. Equation 13 is a consequence of such an approximation. g and g' are two possible values of the same characteristic feature of the tissue, *i.e.* the first moment of the phase function.

The method of claim 1 of the subject patent application uses an approximation of the second order corresponding to the expansion of the phase function to the first three terms: g_0 , g_1 , and g_2 . The claimed equation $\gamma = (1-g_2)/(1-g_1)$ cannot be replaced by Equation 13 of Wu *et al.* because, among other things, the claimed equation refers to different quantities of the tissue: g_2 is the second moment of the phase function, whereas g' in Equation 13 refers to the first moment. In other words, claim 1 and its dependent claims call for an additional parameter characterizing the tissue, g_2 , which Wu *et al.* does not consider. The illustrative example embodiments described in the specification show that the additional g_2 parameter significantly enhances the ability to obtain accurate quantitative information about the scattering and absorption of the tissue.


Because of the above-noted deficiencies, Wu *et al.* could not possibly have rendered the subject matter of claims 1-7 and 12-21 obvious.

BEVILACQUA et al.
Application No. 09/806,831

Applicants respectfully submit that the pending claims are allowable and prompt notification to this effect is respectfully requested.

Respectfully submitted,

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